



Corporate Quality Assurance/Regulatory Affairs

SAFETY AND EFFECTIVENESS SUMMARY

Medline Industries, Inc.

One Medline Place

Mundelein, IL 60060

Phone #: (847) 949-2639

Fax #: (847) 949-2643

Lara N. Simmons

Corporate Regulatory Affairs Manager

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Device Name: Protective Restraint, Limb Holder
Wheelchair Accessory, Limb Holder
Proprietary: Medline Economy Limb Holder, Medline Deluxe Limb
Holder, Medline Cinch-Type Limb Holder, Medline
Padded Limb Holder, Medline Adjustable Limb
Holder, Medline Quick Control Limb Holder, Medline
Modified Cinch-Type Limb Holder.
Common: Limb Restraint

These devices have been legally marketed prior to the date of this submission. The intended use and claims, technological features, materials and physical and mechanical specifications have not been changed.

1.0 General Description

Medline's Limb holders are intended to be utilized as a patient safety device when limited movement of the limb is deemed necessary. The limb holders are all of the same basic design, some with different linings on the cuff, others utilize buckles, hook and loop closures ("velcro") or D-rings. They may be used either at the wrist or ankle and may tie to the bed frame or wheelchair.

The various types of limb holders are discussed as follows:

1. Deluxe Limb Holder - Lined with synthetic fur to minimize chafe and irritation. Hook and loop closure to help prevent tightening or loosening of cuff. Straps adjust via sewn in loops. May tie to bed frame or wheelchair frame. These limb holders are available in either cotton or nylon. Reference Attachment A for a picture of this device. Item is washable.
2. Padded Limb Holder - Lined with synthetic fur to minimize chafe and irritation. Cuff adjusts using a corset buckle that helps prevent tightening or loosening of cuff. Belts

may be detachable or non-detachable at cuff, and adjust via corset buckles. Reference Attachment A for a picture of this device. Item is washable.

3. Quick Control Limb Holder - Lined with synthetic fur to minimize chafe and irritation. Cuff adjusts using a hook and loop closure with two adjustment rings. Reference Attachment A for a picture of this device. Item is washable.

4. Adjustable Limb Holder - Lined with cotton to help minimize chafe and irritation. straps adjust via sewn on loops. Reference Attachment A for a picture of this device. Item is washable. Cuff backing may be Cotton Flannel or Nylon.

5. Cinch-Type Limb Holder - Lined with one-piece foam to minimize chafe and irritation. Hook and loop closure tab will adhere anywhere on the foam backing. Straps adjust via metal "D" rings. Reference Attachment A for a picture of this device. Item may be washed or discarded.

6. Modified Cinch-Type Limb Holder - Lined with one-piece foam to minimize chafe and irritation. Hook and loop closure tab will adhere anywhere on the foam backing. Straps adjust via metal "D" rings. This item differs from the Cinch-Type Limb Holder in that the wrist strap is independent of the anchor strap. Reference Attachment A for a picture of this device. Item may be washed or discarded.

7. Economy Limb Holder - Cuff is made of orthopedic felt. Straps adjust using corset buckles. Reference Attachment A for a picture of this device. Item may be washed or discarded.

8.0 Single Patient Use Limb Holder - Cuff is made of foam that closes with a hook and loop tab with a nylon "D" ring. This item is the same in design as our Cinch-Type Limb Holder but is not washable and is labeled for single patient use only.

A reasonable search of all information known or otherwise presently available to Medline Industries, Inc. has been conducted. Such a search is defined as examining articles in medical literature, FDA literature, and company documents concerning safety and effectiveness information for safety restraints. Following is a summary of and citation to the safety and effectiveness data found in that search.

Specific safety and effectiveness data outlined in the literature include actual as well as potential complications which may occur and are summarized as follows:

Emotional desolation, agitation, fractures, chafing, burns, nerve damage, circulatory impairment, decubitus ulcers, death, and strangulation attributed to incorrect supervision, handling or application of protective restraint devices by medical or paramedical personnel. These incidences seem to be the result of inappropriate patient selection (physically restraining a patient for whom physical restraint is contraindicated), incorrect restraint selection, errors in correctly applying the device, and/or inadequate monitoring of patients when restrained.

When used correctly and for indicated circumstances, protective restraints provide benefits to many patients, such as precluding patients with temporary medical related cognitive deficits from impairing the resolution of their physical problems by involuntarily discontinuing life-support or other needed medical interventions, temporarily reducing the mobility of agitated patients, or limiting the movement of a restrained limb to a desired range or limit.

Medline Industries, Inc. offers a variety of additional materials to help insure the safe and proper use of its patient safety products, including posters and videos. Medline Industries, Inc. stresses the importance of patient monitoring, and that these products should only be used upon advice of a physician or other trained, licensed healthcare professional.

A total of thirteen articles were reviewed for this 510(k) submission. The articles listed in the citation contained pertinent data for establishing the safety and efficacy of protective restraints.

CITATION

Physical Restraints: An FDA Update, American Journal of Nursing From FDA Nurses 1992; 74: November 1992, Mary D. Weick, RN, MSN.

Potential Hazards With Protective Restraint Devices; FDA Medical Alert, dated November 14, 1991; MDA91-3

The Misuse of Physical Restraints in the Confused Patient; This paper was presented by Ms. Barbara Fitzgerald, Ward Sister, Geriatric Unit, St. James Hospital Dublin at the INO Nursing Association for the Elderly Day Conference in April, 1986.

Federal Register/Vol. 57, No. 119/Friday, June 19, 1992/ Proposed Rules

Potential Hazards with Physical Restraint Devices; FDA Safety Alert, dated July 15, 1992

Restraint and Seclusion; Journal of Psychosocial Nursing, June 1985, Vol. 23, No. 6, Janice M. Roper, RN, MS, Adam Courtts, MS Janet Sather, RN, and Rosella Taylor, RN.